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| 10/770,702 | 02/02/2004 | Lev Korzinov | 16491-022001 | 1300 |

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| EXAMINER |
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BERTRAM, ERIC D

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| ART UNIT | PAPER NUMBER |
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3766

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| MAIL DATE | DELIVERY MODE |
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05/24/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/770,702

Applicant(s)

KORZINOV ET AL.

Examiner

Eric D. Bertram

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-19 and 26-58 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 13-19 and 26-58 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/8/2007 has been entered.

Response to Arguments

2. Applicant's arguments filed 5/8/2007 have been fully considered but they are not persuasive. The applicant argues that the heart rate estimates of Zahorian do not describe periods of time when the information content of a biological signal is deemed to be of increased relevance to a particular purpose. Furthermore, the applicant argues that Zahorian does not disclose a cardiac biological signal that includes information describing Zahorian's estimates of the heart rate. The Examiner respectfully disagrees. Since Zahorian is attempting to estimate the heart rate of a fetus, all periods of time of a cardiac biological signal is of increased relevance to determining the current heart rate estimate. This is because the heart rate is a dynamic quantity. Since the goal of Zahorian is to provide the most current and accurate estimate of the heart rate, all periods of time in the incoming signal is of increased relevance to realizing this particular purpose. Furthermore, while there are multiple incoming cardiac biological signals, each signal contains the information necessary to create an estimate. The fact

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that the estimates are produced merely by filtering the incoming signals (i.e., no other signals or information is introduced or added), shows that the incoming signals inherently contain this information; it just must be extracted from other unwanted information and noise. Each incoming signal will continuously provide estimates that will be ranked against other estimates coming from other contemporary signals.

3. Regarding the rejection of claims 27 and 36, "redaction" merely means to put something into a suitable form for publication. In this case, the heart rate estimate that was most meritorious must be put into a form that can be displayed on the remote display. By displaying the estimate, the event is identified as a heart rate. Therefore, the 35 USC 102(b) rejection of claims 13, 14, 16-19, 26-38 and 40-46 is still considered proper.

4. The applicant further argued that since Baker's heart estimates are derived from biological signals, that there is no biological signal that includes estimates of heart rate estimates. The Examiner again disagrees. As shown in figure 1a, a single biological signal, the IR data, is sent to be filtered at step 29 and beyond. The fact that the estimates are produced merely by filtering the incoming signals (i.e., no other signals or information is introduced or added), shows that the incoming signals inherently contain this information; it just must be extracted from other unwanted information and noise. As states in the claims, the biological signal must merely contain "information describing events," and not the events themselves. The 35 USC 102(b) rejection of claims 13-15 and 37-39 is still considered proper.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 13, 14, 16-19, 26-38, 40-46 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Zahorian et al. (US 5,524,631, hereinafter Zahorian). Zahorian discloses a method for determining a figure of merit for cardiac biological signals. Zahorian describes receiving a plurality of cardiac biological signals 2 from a patient using sensor 1, which includes information describing the heart beat and heart rate of the patient (Col. 4, lines 49-67). These signals are then processed to produce a plurality of heart rate estimates, and a figure of merit is determined for each estimate, wherein the figure of merit is based on the quality of the information, specifically continuity constraints and a measure of periodicity (Col. 8, lines 25-40). These figures of merit are then compared to each other and ranked to determine which has the highest ranking, and then the heart rate associated with that figure of merit is handled for medical purposes, while the rest are discarded (see figure 3 and Col. 8, lines 41-49).

7. Regarding claims 17, 18, 30, 31 and 41-43, Zahorian discloses that the estimates are taken over, and associated with, a period of approximately 0.5 seconds (Col. 8, lines 47-48). Furthermore, Zahorian describes determining which signal is the most meritorious by comparing and ranking the signals. Therefore, the signal with the highest figure of merit is placed in a determined to be in the "most meritorious" category.

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8. Regarding claims 19, 27, 35, 36, 40, 45 and 46, Zahorian discloses that the heart rate corresponding to the highest figure of merit is sent to a remote display or through a modem (Col. 9, lines 30-40).

9. Regarding claim 28, if the heart rate is found to be zero, this would inherently be identified as an asystole event.

10. Regarding claim 29, Zahorian discloses that the events are identified by based on a range of normal fetal heart rates (Col. 8, lines 33-36).

11. Regarding claims 33 and 44, Zahorian discloses a graph with a time stamped x-axis that displays the time with the most-meritorious events used to create the signal (see figure 8 and Col. 9, lines 40-47).

12. Regarding claim 58, the information in the biological signal describes the current heart rate state of the fetal heart.

13. Claims 13-15 and 37-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Baker, JR. et al. (US 2002/0137994 A1, hereinafter Baker). Baker discloses a method for determining the merit of cardiac biological signals to determine their quality. Baker describes receiving a plurality of cardiac biological signals describing events (par. [0035-0036]). A weight is assigned to the plurality of signals that is based on a plurality of variables, including signal-to-noise ratio and arrhythmia probability (higher probability = more severe condition) (see claim 15 and par. 0178). Based on these weights, certain events are used to determine a pulse rate, while some events may be rejected if they do not meet certain criteria (See abstract).

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14. Claims 13, 26-30, 33, 37, 41, 44 and 47-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al. (US 4,336,810, hereinafter Anderson).

Anderson discloses a system and method for handling information received from the body. An ECG signal is received that contains information describing arrhythmic events of the heart (Col. 5, lines 56-68). The raw signal is recorded and time stamped so that the time of the event is documented (Col. 8, lines 59-65). The events are compared to known templates to determine the severity of the cardiac condition, i.e., whether or not a known arrhythmia is present (Col. 7, lines 3-9). If the information matches a template, then the event is handled for classification and an arrhythmia counter is updated (Col. 7, lines 17-21). If the information does not match a template, the information is discarded, or set aside, so that it may be given independent consideration (Col. 7, lines 10-13).

15. Regarding claims 27, 28, 49-51, and 54-56, Anderson discloses that the abnormalities that can be identified include tachycardia, bradycardia, and dropped beats (i.e., flutter) (Col. 8, lines 1-5).

16. Regarding claims 48 and 53, Anderson discloses that the ECG data can be analyzed by breaking the signal into different parts by time length (Col. 7, lines 60-65).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday from 8:30-7 EST.

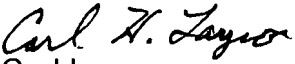
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric D. Bertram
Examiner
Art Unit 3766

EDB


Carl Layno
Supervisory Patent Examiner
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